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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,825	03/30/2004	Theoharis C. Theoharides	51275/147	3056

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,825	THEOHARIDES, THEOHARIS C.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-49* is/are pending in the application.

4a) Of the above claim(s) *40-44 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 40-49 are pending.

The response and amendment filed on May 18, 2007 was received and entered. Claims 45 and 46 are amended. Claims 40-44 and 49 are withdrawn from further consideration due to a previous restriction requirement.

Claims 45-48 are examined on the merits in this office action.

The text of those sections of Title U.S.C. not included in this action can be found in a prior action.

Priority

1. Applicant's claim to subject matter disclosed in the prior applications recited in the amendments received on May 18, 2007 and March 30, 2004 is acknowledged.

2. However, the later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

3. The disclosure of the prior-filed applications, Application No. 09/056,707, filed April 4, 1998, Application No. 09/771,669 filed January 30, 2001, and Application No. PCT/US02/00476, filed January 3, 2002, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of

this application. The applications to which the instant application claims priority do not disclose a medical device coated with an anti-inflammatory compound, as recited in claims 45-48.

4. Thus, priority to the above applications is not granted.

Response to Amendment

5. The amendment to the claims filed on May 18, 2007 is acknowledged, as is applicant's compliance with the requirement of 37 CFR 1.121(c) that the claims be placed on a separate sheet. However, applicant has not complied with the requirement of 37 CFR 1.121(c), (2), which states:

6. *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. **The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived.** Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

7. Specifically, in claim 46, applicant appears to have intended to delete the word "highly" by placing single brackets around the word rather than double brackets. Since the response appears to be a *bona fide* attempt to comply with 37 CFR 1.121(c), and in the interest of compact prosecution, it is assumed for examination purposes that applicant intended to delete the word "highly" from the claim.

Claim Rejections - 35 USC § 112

8. Claim rejections under 35 USC § 112 have been withdrawn due to amendment.

Declarations under 37 CFR 1.132

9. The declaration under 37 CFR 1.132 filed May 18, 2007 is insufficient to overcome the rejection of claims 45-48 under 35 U.S.C. 103 as set forth in the last Office action because:

10. It refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. For example, the declaration states interest in certain medical devices coated with nutraceutical compositions, such as those of the instant application. The declaration fails to disclose whether the devices of interest are, in fact, those claimed in the instant application. See MPEP § 716.

11. Further, the declaration only states that there are serious negotiations with American companies, but fails to give any definitive commercial success. The term "serious negotiations" could refer to any legal negotiations, and is not sufficient to give meaningful commercial success to the claimed invention. There is also no evidence that the parties interested in the claimed invention are aware of the products taught by

the above-cited references, and how the claimed invention would result in commercial success not experienced by the products taught by the cited references.

12. Therefore, the declaration is insufficient to overcome the rejection of the cited claims under 35 U.S.C. 103.

Claim Rejections - 35 USC § 102

13. Claim 45 stands rejection under 35 U.S.C. 102(b) as being anticipated by Shikani et al. (US Pat. 5,762,638, 1998). Claim 45 recites a medical device for implantation in or upon tissues, wherein said device is coated with an anti-inflammatory composition.

14. Shikani teaches an implantable medical device coated with an anti-inflammatory composition (col. 10, lines 1-25).

15. Applicant argues that the coating of the device taught by Shikani does not meet the claim limitation, "an anti-inflammatory composition". It is noted that the polymer coating comprising an anti-infection and anti-inflammatory composition recited by Shikani is an anti-inflammatory composition, and therefore meets the claimed limitation.

16. In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a flavonoid compound) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

17. Therefore, claim 45 of the instant application is anticipated by Shikani.

Claim Rejections - 35 USC § 103

18. Claims 45-48 stand rejected under 35 U.S.C. 103(a) as being obvious over Morrison (GB 2098506 A, 1982) and Hwang et al. (US Pat. 5,948,814, 1999) in view of Theoharides (US Pub. 20020176902). Claim 45 recites a medical device for implantation in or upon tissues coated with an anti-inflammatory composition. Claim 46 further limits claim 45 by reciting that the anti-inflammatory composition comprises a non-bovine, highly sulfated proteoglycan and a flavonoid compound. Claims 47 and 48 further limit claim 46 by reciting that the proteoglycan is chondroitin sulfate, and that the flavonoid compound is quercetin, myricetin or genistein, respectively.

19. Please note that applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120, as discussed above. Briefly, the disclosure of the prior-filed applications (US Application 09/056,707, US Application 09/771,669 and PCT/US02/00476) fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The applications to which the instant application claims priority do not disclose a medical device coated with an anti-inflammatory composition.

20. Morrison teaches an implantable medical device coated with a composition comprising non-bovine highly sulfated proteoglycan (specifically, chondroitin sulfate

from shark cartilage; p. 3, lines 55 and 69-74). Morrison does not teach that the coating comprises a flavonoid compound.

21. Hwang et al. teaches an implantable medical device comprising a flavonoid compound (specifically, genistein; col 7, lines 39-47). Although Hwang et al. do not teach that the flavonoid compound is coating the implantable medical device, it would be inherent to the construction of the device that the flavonoid compound would be present on or coating a surface.

22. Theoharides teaches an anti-inflammatory composition comprising a heavily sulfated, non-bovine proteoglycan (specifically, chondroitin sulfate) and a flavonoid compound (including quercetin, myricetin and genistein; see claims 1 and 5).

23. At the time of the invention, implantable medical devices coated with chondroitin sulfate and flavonoid compounds (specifically, genestein) were known in the art, as taught by Morrison and Hwang et al. It was also known that chondroitin sulfate and flavonoid compounds (including quercetin, myricetin and genistein) could be combined in an anti-inflammatory composition, as taught by Theoharides. Further, Morrison discusses the desirability for the inclusion of chondroitin sulfate in implantable medical devices to increase the acceptance of implants (p. 1, lines 35-54). Hwang teaches that implants comprising quercetin are desirable for the treatment of cystic fibrosis. One of ordinary skill in the art would therefore be motivated to coat the implant taught by Hwang with chondroitin, as taught by Morrison. One of ordinary skill in the art would have a reasonable expectation of success in combining the teaching discussed above because Theoharides teaches that chondroitin sulfate and quercetin are compatible in a

composition, and because both compounds are known to be compatible components of medical devices, as taught by Morrison and Hwang. It would therefore have been obvious to one skilled in the art to combine the teachings to produce the claimed medical device coated with an anti-inflammatory composition comprising chondroitin sulfate and genestein.

24. One skilled in the art would have a reasonable expectation of success combining the teachings discussed above because medical devices coated with both chondroitin sulfate and genestein were known in the art at the time of the invention, as taught by Morrison and Hwang et al, and chondroitin sulfate and genestein were known in the art to be compatible ingredients in an anti-inflammatory composition, as taught by Theoharides. It would therefore have been obvious to one of ordinary skill in the art to combine the teachings discussed above to arrive at the claimed invention.

25. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

26. Applicant argues that Shikani does not meet the claim limitations of claim 45, specifically that Shikani does not teach a device coated with "an anti-inflammatory composition". Applicant further argues that Shikani does not show a device wherein the coating comprises a flavonoid composition. Applicant argues that Hwang and Theoharides are not analogous art, and that Hwang does not disclose coated devices.

Applicant further agues that there is no motivation to combine the teachings discussed above. Applicant further argues that the secondary considerations presented in the declaration under CFR 1.132 are sufficient to overcome the rejections under 35 U.S.C. 103.

27. . In response to applicant's argument that the coating of the device taught by Shikani does not meet the limitation recited in claim 45, "an anti-inflammatory composition", it is noted that the polymer coating comprising an anti-infection and anti-inflammatory composition recited by Shikani is an anti-inflammatory composition, and therefore meets the claimed limitation. In response to applicant's argument that Shikani fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a flavonoid compound) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

28. In response to applicant's argument that Hwang is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Hwang teaches the use of flavonoids in implantable medical devices. Applicant's field of endeavor relates to implantable medical devices comprising flavonoids. Therefore, Hwang is analogous art. Applicant further states that Hwang does not disclose coated

devices. However, Hwang et al. teaches an implantable medical device comprising a flavonoid compound (specifically, genistein; col 7, lines 39-47). Although Hwang et al. do not teach that the flavonoid compound is coating the implantable medical device, it would be inherent to the construction of the device that the flavonoid compound would be present on or coating a surface. Therefore, Hwang teaches devices that are coated with a flavonoid compound.

29. . In response to applicant's argument that Theoharides is nonanalogous art, the reference is deemed to be reasonably pertinent to the particular problem with which the applicant was concerned. The problem with which the applicant was concerned was the preparation and uses of anti-inflammatory compositions. Theoharides teaches an anti-inflammatory composition comprising the same ingredients disclosed in the instant application. Therefore, Theoharides is analogous art.

30. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the references is found in Theoharides, Morrison and Hwang, as discussed above. Further, Morrison discusses the desirability for the inclusion of chondroitin sulfate in implantable medical devices to increase the acceptance of implants (p. 1,

lines 35-54). Hwang teaches that implants comprising quercetin are desirable for the treatment of cystic fibrosis. One of ordinary skill in the art would therefore be motivated to coat the implant taught by Hwang with chondroitin, as taught by Morrison. One of ordinary skill in the art would have a reasonable expectation of success in combining the teaching discussed above because Theoharides teaches that chondroitin sulfate and quercetin are compatible in a composition, and because both compounds are known to be compatible components of medical devices, as taught by Morrison and Hwang. Therefore, the suggestion to combine the references is provided by the teachings discussed above.

31. The declaration under 37 CFR 1.132 filed May 18, 2007 is insufficient to overcome the rejection of claims 45-48 based upon the rejection under 35 U.S.C. 103 as set forth in the last Office action because:

32. It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. For example, the declaration states interest in certain medical devices coated with nutraceutical compositions, such as those of the instant application. The declaration fails to disclose whether the devices of interest are, in fact, those claimed in the instant application. See MPEP § 716.

33. Further, the declaration only states that there are serious negotiations with American companies, but fails to give any definitive commercial success. The term "serious negotiations" could refer to any legal negotiations, and is not sufficient to give

meaningful commercial success to the claimed invention. Further, there is no evidence that the parties interested in the claimed invention are aware of the products taught by the above-cited references, and how the claimed invention would result in commercial success not experienced by the products taught by the claimed references.

34. Therefore, the declaration is insufficient to overcome the rejection of the cited claims under 35 U.S.C. 103.

Conclusion

35. No claims are allowed.

36. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A Davis/
Primary Examiner, AU 1651